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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,163	11/20/2003	Arrigo DeBenedetti	0101611/0507550	8977

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EXAMINER
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ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

NOTIFICATION DATE	DELIVERY MODE
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12/01/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@fbtlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/718,163	<b>Applicant(s)</b> DEBENEDETTI ET AL.	
	<b>Examiner</b> J. E. Angell	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-13,15-25,27-41 and 43-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 and 41 is/are allowed.
- 6) ☒ Claim(s) 4,17,27 and 44 is/are rejected.
- 7) ☒ Claim(s) 1,3-12,15-25,27-40 and 43-56 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/28/08 has been entered.
2. Claims 1, 3-13, 15-25, 27-41, 43-56 are currently pending and are addressed herein.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 4, 17, 27, 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. The instant claims are drawn to an expression vector that encodes a DNA sequence encoding a messenger RNA sequence. One of ordinary skill in the art would recognize the term “expression vector” as meaning a DNA vector which comprises DNA sequences that encode mRNA sequences. It is noted that claims 4 and 27 explicitly encompass administering a DNA sequence by administering an expression vector that encodes the DNA sequence, while claims 17 and 44 explicitly encompass administering

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an mRNA by administering an expression vector encoding a DNA sequence encoding the mRNA. Furthermore, the only expression vector described in the specification is the BK, which appears to be an expression vector comprising DNA sequence which encodes mRNA sequence (e.g., see Figure 1; Example 1; etc.) Therefore, in this case, it would not be clear to one of ordinary skill in the art how an "expression vector" could encode a DNA sequence that further encodes a mRNA sequence as the term "encode" would be understood to mean a sequence that is derived from the vector sequence such as by transcription or translation. Therefore, the claims, as written are indefinite because it is unclear how the DNA sequence could be encoded by the expression vector. It is noted that amending the claims such that they read on an expression vector that comprises a DNA sequence which encodes a messenger RNA would obviate this rejection. Alternatively, amending the claims such that they read on an expression vector that encodes the messenger RNA would be another alternative that would obviate the rejection.

### ***Claim Objections***

6. Claims 1, 5-9, 11, 12 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 16-24. Claims 27-34, 36-40 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 43-56. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

7. In the instant case claim 1 is drawn to a method comprising administering a DNA sequence to a cell wherein the DNA sequence encodes a functional mRNA sequence, while claims 16 is drawn to a method of administering a functional mRNA sequence to a cell by administering an expression vector which produces the functional mRNA sequence. Claim 17 indicates that the expression vector encodes a DNA sequence which encodes the mRNA. Therefore, claims 1, 16 and 17 are substantially duplicate claims. Claims 5-9, 11, 12 depend from claim 1 and mirror claims 18-24 which depend from claim 17. Similarly, claim 27 is drawn to a method of treatment comprising administering a DNA sequence to a mammal wherein the DNA sequence encodes a functional mRNA sequence, while claim 43 is drawn to a method of administering a functional mRNA sequence to a mammal by administering an expression vector which produces a functional mRNA sequence. Claim 44 indicates that the expression vector encodes a DNA sequence that encodes the mRNA. Therefore, claims 27, 43 and 44 are substantially duplicate claims. Claims 28-34, 36-40 depend from claim 27 and mirror claims 45-56 which depend from claim 44. Furthermore, any claim which depends on an objected claim is also objectionable. Accordingly, claims 3, 4, 10, 35 are objected to for depending on objectionable claims.

#### ***Response to Arguments***

8. Applicant's arguments, filed 8/28/08, have been fully considered and are persuasive, in view of the Declaration of Dr. DeBenedetti under 37 CFR 1.132 filed 8/28/08, which has also been fully considered. Accordingly, the previous rejections have

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been withdrawn. However, upon further consideration, new grounds of rejection/objection are set forth for the reasons indicated herein.

***Allowable Subject Matter***

9. Claims 13 and 41 are allowed.

***Attempt to Resolve Pending Issues***

A telephone call was made to Applicants representative (Stephen Albainy-Jenei) on 11/21/08 to attempt to resolve the pending issues by Examiners Amendment; however, the Examiner was unsuccessful in making contact.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/  
Primary Examiner, Art Unit 1635